

## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference <b>02180.0001P1</b>	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. <b>PCT/US2004/040823</b>	International filing date ( <i>day/month/year</i> ) <b>06 December 2004 (06.12.2004)</b>	Priority date ( <i>day/month/year</i> ) <b>04 December 2003 (04.12.2003)</b>	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant <b>BIOFILMS STRATEGIES, INC.</b>			

- This International preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
- This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

- This report contains indications relating to the following items:

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> Box No. I  | Basis of the report   |
| <input type="checkbox"/> Box No. II            | Priority  |
| <input type="checkbox"/> Box No. III           | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input checked="" type="checkbox"/> Box No. IV | Lack of unity of invention  |
| <input checked="" type="checkbox"/> Box No. V  | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI            | Certain documents cited   |
| <input type="checkbox"/> Box No. VII           | Certain defects in the international application  |
| <input type="checkbox"/> Box No. VIII          | Certain observations on the international application   |

- The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 740 14 35 Form PCT/IB/373 (January 2004)	Date of issuance of this report <b>07 June 2006 (07.06.2006)</b>
	Authorized officer  <b>Simin Baharlow</b>  Telephone No. +41 22 338 71 30

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

# PCT

REC'D 06 APR 2006

WIPO

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:  
CHRISTOPHER L. CURFMAN  
NEEDLE & ROSENBERG, P.C.  
SUITE 1000  
999 PEACHTREE STREET  
ATLANTA, GA 30309-3915

Date of mailing  
(day/month/year)

04 APR 2006

Applicant's or agent's file reference

FOR FURTHER ACTION

See paragraph 2 below

02180.0001PI

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/40823

06 December 2004 (06.12.2004)

04 December 2003 (04.12.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(8): A61K 35/66, 35/74, 35/20; C12P 1/00, 1/04 and US Cl.: 424/115; 435/41, 170

Applicant

BIOFILMS STRATEGIES, INC.

I. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US  
Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
Facsimile No. (571) 273-3201

Date of completion of this opinion  
22 December 2005 (22.12.2005)

Authorized officer  
Vera Afremova  
Telephone No. (571) 272-1600

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/40823

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed  
☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing  
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper  
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.  
☐ filed together with the international application in electronic form.  
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/40823

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees
  - ☐ paid additional fees under protest and, where applicable, the protest fee
  - ☐ paid additional fees under protest but the applicable protest fee was not paid
  - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
  - ☒ not complied with for the following reasons:  
See the lack of unity section of the International Search Report (Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☐ all parts.
  - ☒ the parts relating to claims Nos. 1-14

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US04/40823

**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)

Claims NONE YES

Claims 1-14 NO

Inventive step (IS)

Claims NONE YES

Claims 1-14 NO

Industrial applicability (IA)

Claims 1-14 YES

Claims NONE NO

2. Citations and explanations:

Please See Continuation Sheet

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US04/40823

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1-3, 6-8 and 10-13 lack novelty under PCT Article 33(2) as being anticipated by US 6,051,552 (Reid et al).

Claims are directed to a composition for treating biofilms on a surface wherein the composition comprising a cell-free fermentate. Some claims are further drawn to the cell-free fermentate from lactic bacteria including *Lactobacillus acidophilus*. Some claims are further drawn to incorporation of carriers and adjuvant into the composition. Some claims are further drawn to the cell-free fermentate composition obtained by culturing bacteria on fermentable substrates including sugars and separating the cell-free fermentate by centrifugation and/or filtration.

US 6,051,552 (Reid et al) discloses a biosurfactant composition for inhibiting microbial biofilm formation (abstract). The biosurfactant is a cell-free fermentate (column 3, line 53-57) obtained from lactic bacteria including *Lactobacillus acidophilus* (column 4, lines 62-65) by culturing bacteria on conventional culture media that include fermentable substrates and separating the cell-free fermentate by centrifugation and/or filtration (column 5, lines 4-20). Carriers and adjuvant are incorporated into the biosurfactant composition (column 8, lines 1-10). Thus, the cited patent teaches identical compositions as claimed.

Claims 1, 4 and 5 lack novelty under PCT Article 33(2) as being anticipated by US 6,555,356 (Kjelleberg et al).

Claims are directed to a composition for treating biofilms on a surface wherein the composition comprising a cell-free microbial fermentate derived from *Delisea pulchra*.

US 6,555,356 teaches a composition for treating biofilms on a surface that is capable to inhibit adhesion of marine isolates to artificial surfaces wherein the composition comprising a cell-free microbial fermentate derived from *Delisea pulchra* (column 8, lines 55-67). Thus, the cited patent teaches identical composition as claimed.

Claims 1-3 and 6-14 lack novelty under PCT Article 33(2) as being anticipated by US 4,929,445 (Vandenberg et al).

Claims are directed to a composition for treating biofilms on a surface wherein the composition comprising a cell-free fermentate. Some claims are further drawn to the cell-free fermentate from lactic bacteria including *Pediococcus acidilactici*. Some claims are further drawn to incorporation of carriers and adjuvant into the composition. Some claims are further drawn to the cell-free fermentate composition obtained by culturing bacteria on fermentable substrates and separating the cell-free fermentate by centrifugation and/or filtration. Some claims are further drawn to incorporation of non-fat milk derivatives into the composition.

US 4,929,445 (Vandenberg et al) discloses a bacteriocin-containing composition capable to inhibit bacteria forming biofilms on a surface wherein the composition comprising a cell-free fermentate derived from *Pediococcus acidilactici*. The composition is obtained by culturing bacteria on fermentable substrates, separating the cell-free fermentate by centrifugation and filtration; and incorporating non-fat milk derivatives into the composition. The cited patent also teaches culturing bacteria on various fermentable substrates including milk derivatives (column 4, lines 42-47). Thus, the final product obtained by the method of fermentation contains identical components and has identical activity as required for the claimed product.

Claims 1-14 lack an inventive step under PCT Article 33(3) as being obvious over US 6,051,552 (Reid et al) and US 4,929,445 (Vandenberg et al).

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US04/40823

**Supplemental Box**  
In case the space in any of the preceding boxes is **not sufficient**.

Claims are directed to a composition for treating biofilms on a surface wherein the composition comprising a cell-free fermentate. Some claims are further drawn to the cell-free fermentate from lactic bacteria including *Lactobacillus acidophilus* and *Pediococcus acidilactici*. Some claims are further drawn to incorporation of carriers and adjuvant into the composition. Some claims are further drawn to the cell-free fermentate composition obtained by culturing bacteria on fermentable substrates and separating the cell-free fermentate by centrifugation and/or filtration. Some claims are further drawn to incorporation of non-fat milk derivatives into the cell-free fermentate composition.

The cited patents US 6,051,552 (Reid et al) and US 4,929,445 (Vandenberg et al) disclose cell-free fermentate compositions for inhibiting microbial adhesion and treating biofilms on surfaces. The compositions are obtained by culturing bacteria on conventional media with various fermentable substrates including sugars, milk derivatives, etc. and further separating the cell-free fermentates by centrifugation and filtration. The final products obtained by the methods of bacterial fermentation contain substantially the same, if not identical components, and they have identical biofilm inhibiting activity as required for the claimed product. Thus, the prior art biosurfactant compositions are obvious variants of the claimed product(s). Therefore, the claimed invention lacks inventive step.